FEB 1 1 2002

K013944
P1/2

510 (K) Summary

Submitter:	Jostra AG Hechinger Straße 38 72145 Hirrlingen Germany
Contact Person:	Kathleen Johnson P. O. Box 218 Oxford, PA 19363 Phone: (610) 932-7738 Fax: (610) 932-7366
Date Prepared:	November 21, 2001
Device Trade Name:	Jostra Dual-stage Venous Cannulae
Common/Usual Name:	Two-Stage Venous Cannulae
Classification Names:	Cardiopulmonary Bypass Vascular Cannula Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Predicate Device:	Medtronic DLP Two-Stage Venous Cannulae

Device Description:

The Jostra Two-Stage Venous Cannulas are single, sterile devices for single use only and not to be resterilized by the user. The cannulas are to be used to divert blood from the patient to the extracorporeal circuit by draining blood simultaneously from the Right atrium and the Inferior vena cava. The cannulae are made from polyvinyl chloride (PVC) and range in size from 32Fr./40Fr. to 36Fr./51Fr. with a variety of tips and with or without attached connectors.

Indications for use:

The Jostra Two-Stage Venous Cannulae are designed to be used as perfusion cannulae to divert venous blood from the patient during surgery requiring extracorporeal circulation for up to 6 hours.

Statement of Technical Characteristics Comparison:

The Jostra Two-Stage Venous Cannula have the same intended use and design as the Medtronic DLP Two-Stage Venous Cannula. The Jostra Two-Stage Venous Cannula are available in sizes 32/40Fr to 36/51Fr. The Medtronic DLP Two-stage Venous cannula range in sizes from 28/36Fr. to 36/51Fr. Comparative testing has demonstrated that these differences do not affect safety and effectiveness.

Non-Clinical Testing:

Biocompatibility and performance testing was performed to demonstrate substantial equivalency to the predicate device.

Performance testing included:

Flow-Pressure curves
Kink Resistance
Bond Strength
Leakage Test

Additionally, in-vitro testing was performed to determine the effects on cellular components.

Conclusion:

Performance, and in-vitro testing demonstrate that the Jostra Two-Stage Venous Cannulae are "substantially equivalent" to the predicate devices in intended use, principles of operation, materials, design, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1 2002

Ms. Kathleen Johnson
Regulatory Affairs, Submissions Manager
c/o Jostra-Bentley Corp.
Jostra AG
478 Media Road
Oxford, PA 19363

Re: K013944
Trade Name: Jostra Dual Stage Venous Return Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing.
Regulatory Class: Class II (two)
Product Code: DWF, DTL
Dated: November 21, 2001
Received: November 29, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013944

510(k) Number:

Device Name: Jostra Two-Stage Venous Cannulas

Indications for Use
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013944